Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of Oral Glutamine Administration on Reduction of Myocardial Dmage After Open Heart Surgery, a Prospective Randomized Clinical Trial Study

Protocol summary

Study aim

Evaluation of oral administration of glutamine to improve cardiovascular function in patients undergoing open heart surgery and to evaluate the effect of this combination on surgical outcomes.

Design

The randomized clinical trial with the intervention and control group, parallel groups, double blinded

Settings and conduct

A randomized clinical trial that is performed on patients undergoing non-emergency open heart surgery who are referred to Fatemeh Zahra Hospital in Sari. The population studied in this study includes all adult patients (aged 18-80) including men and women who have inclusion criteria for research. Patients and therapists are not aware of the type of drug contained in powders (glutamine, Avicel and starch), and only the researcher knows the code based on the code (code A or code B)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, Patients who are candidates for open heart surgery, Sinus rhythm in the patient before surgery Exclusion criteria: Age over 80 years, History of chronic lung, liver, kidney and thyroid diseases and heart failure, Total Bilirubin more than 10 mg / dL, Creatinine clearance less than 30 ml / min

Intervention groups

A total of 106 patients with open heart surgery candidates were randomly divided into two groups of 53. For the first group, 0.5 g / kg of glutamine is taken orally once a day, and for the control group, placebo (Avicel and starch powder) is added. The drug forms of placebo are prepared in terms of the appearance of glutamine.

Main outcome variables

Duration of admission to ICU, Duration of hospitalization, Mortality after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151109024975N10**
Registration date: **2018-08-29, 1397/06/07**
Registration timing: **prospective**

Last update: **2019-07-27, 1398/05/05**
Update count: **1**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Gohar Eslami

Name of organization / entity

Mazandaran University of Medical Scienses

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-21, 1397/06/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

2018-09-21, 1397/06/30

Actual recruitment end date

2019-04-19, 1398/01/30

Trial completion date

2019-04-19, 1398/01/30

Scientific title
Evaluation of Oral Glutamine Administration on Reduction of Myocardial Dmage After Open Heart Surgery, a Prospective Randomized Clinical Trial Study

Public title
Effect of Glutamine on Reducing Myocardial Damage

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Candidate for open heart surgery Preoperative sinus rhythm Normal function of liver, renal system, pulmonary system and thyroid

Exclusion criteria:
Emergency patients Serious water and electrolyte disorders Unwillingness to co-operate with the patient History of chronic lung, liver, kidney and thyroid diseases and heart failure Age over 80 years Pregnant and lactating women Patients who are hypersensitive to glutamine or who are banned in any way by their administration of glutamine Total Bilirubin more than 10 mg / dL Creatinine clearance less than 30 ml / min Absolute Absence of Intestinal Feeding

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **106**
Actual sample size reached: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
Random method and description of each method: simple randomization After determining the size of the sample, 106 people, 53 in the control group and 53 in the intervention group were considered. By co-ordinating medical records, this number was considered average for the duration of the appointment, and then the list of individuals was determined. The list was prepared based on the patients' turn-by-turn and then, using the random numbers table, the numbers of the control and intervention group were determined and compared to the coordination for the next steps.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the informed consent form, patients are told that they may receive glutamine or placebo (Avicel powder and starch). Therefore, patients are not aware of their treatment group. Since patients and therapists are not aware of the type of drug contained in powders (glutamine, Avicel and starch), only the researcher is aware of the powder on the package code (code A or code B).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
•Ethics committee of Mazandaran University of Medical Sciences

Street address
Artesh Blvd., Fatemeh-zahra hospital Mazandaran University of Medical Scienses

City
Sari

Province
Mazandaran

Postal code
48157-33971

Approval date
2017-12-24, 1396/10/03

Ethics committee reference number
IR.mazums.REC.1396.3093

Health conditions studied

1

Description of health condition studied
Acute coronary syndrome

ICD-10 code
I24.0

ICD-10 code description
Acute coronary thrombosis not resulting in myocardial infarction

Primary outcomes

1

Description
Myocardial injury after open heart surgery

Timepoint
The day before the surgery (before the intervention) and the first and second days after surgery

Method of measurement
SOFA score

Secondary outcomes

1

Description
Duration of admission to ICU
Timepoint
Duration of admission
Method of measurement
Patients follow up

2

Description
Duration of hospitalization
Timepoint
Duration of admission
Method of measurement
Patients follow up

3

Description
Mortality
Timepoint
Duration of admission
Method of measurement
Patients follow up

Intervention groups

1

Description
Intervention group: A dose of 0.5 g / kg of glutamine powder is administered orally once a day during the ICU for patients.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group received placebo (Avicel powder and starch). The frequency and duration of use of placebo in the control group were similar to oral administration of glutamine powder in the intervention group (once a day and up to the time of discharge from the ICU). Patients undergoing coronary artery bypass grafting, the drug is fed through the nasopharyngeal tube. The placebo is structurally similar to glutamate powder.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh-zahra hospital Mazandaran University of Medical Scienses
Full name of responsible person
Gohar Eslami
Street address
Artesh Blvd., Center of the heart of Mazandaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi
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Vice Chancellor for Research of Mazandaran University of Medical Sciences, Moalem Square
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person
Gohar Eslami

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available